REMARKS

This application pertains to a novel abuse-proofed dosage form.

Claims 1, 2, 4, 7, 8, 27- 29, 31, 41 and 42 are pending; claims 41 and 42 being added by this amendment.

Claims 1, 2, 4, 7, 8, 27-29 and 31 stand rejected under 35 U.S.C. 112, second paragraph, because the Examiner finds the "amount sufficient" of component C required to result in a breaking strength of at least 500 N as not being defined in the specification.

Initially, it should be noted that the expression "amount sufficient" is widely used and generally accepted in U.S. Claim language. To this end, Applicants did a search of the USPTO records and found 23,443 U.S. patents having that expression in their claims. The list obtained from the USPTO website is attached. Further, the accompanying Declaration of Dr. Johannes Bartholomäus points out, in section 4.3(b), that the minimum quantity of polkyethylene oxide that is required in order to yield dosage forms having a breaking strength of at least 500N is a function of the molecular weight, that the threshold value varies from polymer to polymer, and that the amount required can be found by *routine experimentation.*

Still further, the specification, in the Example at page 39, provides a simple experimental technique by which the amount of component C required to achieve a

breaking strength of 500N can be determined.

Accordingly, the "amount sufficient" in each case can be determined by a known experimental method with a reasonable amount of experimentation, and the expression "amount sufficient" is therefore not indefinite. The rejection of claims 1, 2, 4, 7, 8, 27-29 and 31 under 35 U.S.C. 112, second paragraph should therefore now be withdrawn.

Claims 1, 2, 4, 7, 8, 27-29 and 31 stand rejected under 35 U.S.C. 103(a) as obvious over Oshlack et al (US 2003/0064099/A1) in view of Zhang et al (Pharm. Dev. Teach. 1999, 4, 241-250) and Maggi et al (Biomaterials 2002, 23, 1113-1119) as stated in the office action of 1/17/07.

Applicants have already pointed out that nothing in Oshlack teaches or suggests how to achieve a breaking strength of 500N.

To this, the Examiner argues that Oshlack teaches a controlled release oral dosage form of an opioid analgesic comprising polyethylene oxide of molecular weights varying from 1,000,000 to 10,000,000; that they have the same polymer of the same molecular weight, wax, binders, etc. and that they are also prepared via melt extrusion techniques. The Examiner further argues that it would be obvious that the breaking strength and tablet characteristics can be manipulated as disclosed by Maggie et al to produce tablets capable of having a breaking strength of at least 500N.

Zhang is cited by the Examiner to show that polyethylene oxide polymers of molecular weights of 1,000,000 and 7,000,000 are stable to the hot melt extrusion technique. Nowhere, however, does this reference teach or suggest anything about even the possibility of a 500 N breaking strength, let alone how such might be achieved!

The Examiner asserts at page 4 of the office action that Maggi teaches both heating and compression, and therefore that it would be obvious to one skilled in the art to apply heat and different compression forces to generate the desired breaking force.

There is, of course, absolutely nothing in the combined references that would teach or suggest that a breaking strength of 500 N is even achievable, by any technique. Certainly, none of the cited references discloses such a breaking strength anywhere.

Moreover, the accompanying Declaration of Dr. Johannes Bartholomäus, in which Examples 1 and 2 were prepared in accordance with Oshlack et al, clearly shows that Oshlack's dosage forms do not achieve a breaking strength of 500N.

At page 5 of the accompanying Declaration of Dr. Johannes Bartholomäus, it is again pointed out that the dosage forms of Oshlack et al can be chewed spontaneously, and therefore that they cannot possibly have a breaking strength of 500 N.

Once again it must be emphasized that nowhere in any of the references cited,

whether taken individually or in any combination, is there any hint of any steps that might be taken to achieve a breaking strength of 500N. No person skilled in the art reading the cited references could possibly ever arrive at a dosage form having a breaking strength of 500N. The Examiner has not pointed to anything in the references that would have anything to do with a breaking strength of at least 500N.

The Examiner has tried to explain why she cited e.g. the Maggi reference, and what she intended to show. Nevertheless, the Examiner has not pointed to anything in the references cited that would teach or suggest to one skilled in the art how a breaking strength of 500 N can be achieved. The accompanying Declaration of Dr. Johannes Bartholomäus points out that this breaking strength cannot be achieved by the compositions and techniques of Oshlack.

Clearly, neither Zhang nor Maggi teach or suggest how a breaking strength of 500 N could be achieved with the compositions of Oshlack. As previously pointed out, Zhang has no teaching or suggestion of how a breaking strength of at least 500 N. might be obtained, nor is there even a recognition of breaking strength as a parameter to be considered! It has also previously been pointed out that Maggi shows that a compression force from 10 KN to 30 KN in a tablet formulated with PEO 900,000 (below Applicants minimum molecular weight range) made some difference in crushing strength (see A1 in Table 2), but when using the higher molecular weight PEO 4,000,000 (which is within Applicants molecular weight range), the increase in crushing strength was negligible and was, in fact, within the error limits of the test (see B1 in

Table 2)! This would clearly teach ***away*** from Applicants' claims, which require a molecular weight of component (C) of between 1 and 15 million! For Applicants' molecular weight range of component (C), Maggi would suggest that compression has absolutely no influence on crushing strength.

Applicants' claims cannot therefore be seen as obvious over the cited references, and the rejection of claims 1, 2, 4, 7, 8, 27-29 and 31 under 35 U.S.C. 103(a) as obvious over Oshlack et al (US 2003/0064099/A1) in view of Zhang et al (Pharm. Dev. Teach. 1999, 4, 241-250) and Maggi et al (Biomaterials 2002, 23, 1113-1119) should now be withdrawn.

Claims 1, 2, 4, 7, 8, 27-29 and 31 stand rejected under 35 U.S.C. 103(a) as obvious over Oshlack et al (US 6,733,783 B2) in view of Zhang et al (Pharm. Dev. Teach. 1999, 4, 241-250) and Maggi et al (Biomaterials 2002, 23, 1113-1119) as stated in the office action of 1/17/07.

Applicants have already pointed out why this combination of references cannot possibly lead to the abuse-proofed dosage form recited in the rejected claims.

In response, the Examiner argues that it would be obvious to manipulate the breaking strength and tablet characteristics as disclosed by Maggi with an expectation of achieving a breaking strength of 500N. This is simply not correct. As pointed out before, there is absolutely nothing in any of the references cited that would even

suggest that a breaking strength of 500 N is possible, and certainly nothing that would lead those skilled in the art to a technique for achieving that breaking strength. By contrast, as discussed previously as well as above, Maggi would teach away from Applicants invention, by showing that compression has absolutely no influence on crushing strength. In the Maggi experiments using PEO of a molecular weight 4,000,000 (which is within Applicants molecular weight range), the increase in crushing strength was negligible and was, in fact, within the error limits of the test. How does the Examiner think that such a teaching would ever lead those skilled in the art to Applicants' breaking strength of 500 N? The Examiner asserts that Maggi was cited to show both heating and compression, and that this reference would make it obvious to heat and compress the dosage forms to somehow arrive at the 500 N breaking strength recited in Applicants' claims. This is simply not logical. Given that Maggi shows a negligible increase in crushing strength which increase was so negligible that did not even exceed the experimental error, it makes absolutely no sense to argue that Maggi would lead those skilled in the art to use compression and heat to increase the breaking strength of a dosage form to at least 500N.

There is no way that any combination of the cited references could possibly lead to Applicants novel dosage form having a breaking strength of at least 500N, and the rejection of claims 1, 2, 4, 7, 8, 27-29 and 31 under 35 U.S.C. 103(a) as obvious over Oshlack et al (US 6,733,783 B2) in view of Zhang et al (Pharm. Dev. Teach. 1999, 4, 241-250) and Maggi et al (Biomaterials 2002, 23, 1113-1119) as stated in the office action of 1/17/07 should now be withdrawn.

Claims 1, 2, 4, 7-8, 29 and 31 stand provisionally rejected for obviousness type double patenting over claims 1-4, 7-11, 25-27 and 30 of copending application No. 10/567,594. This provisional rejection is obviated by the accompanying Terminal Disclaimer.

Claims 1, 2, 4, 7, 8, 29 and 31 stand provisionally rejected for obviousness type double patenting over claims 1-4, 7-11, 25-27 and 30 of copending application No. 11/349,537. This provisional rejection is obviated by the accompanying Terminal Disclaimer.

Claims 1, 2, 4, 7, 8, 29 and 31 stand provisionally rejected for obviousness type double patenting over claims 1-4, 7, 9-14 and 22 of copending application No. 10/890,763. This provisional rejection is obviated by the accompanying Terminal Disclaimer.

Claims 1, 2, 4, 7, 8, 29 and 31 stand provisionally rejected for obviousness type double patenting over claims 1-4, 6, 7-10 and 14-16 of copending application No. 11/462,216. This provisional rejection is obviated by the accompanying Terminal Disclaimer.

In view of the present amendments and remarks it is believed that claims 1, 2, 4,

7, 8, 27-29 and 31 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,
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